DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 2 4 2010

Re: SAVELLA
Patent Nos. 6,602,911 and 6,992,110
Docket Nos.: FDA-2009-E-0230
FDA-2009-E-0231

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 6,602,911 and 6,992,110, filed by Cypress Bioscience, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for SAVELLA (milnacipran hydrochloride), the human drug product claimed by the patents.

The total length of the regulatory review period for SAVELLA (milnacipran hydrochloride) is 2,571 days. Of this time, 2,177 days occurred during the testing phase and 394 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 2, 2002.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 2, 2002.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 18, 2007.

   FDA has verified the applicant's claim that the new drug application (NDA) 22-256 was submitted on December 18, 2007.

3. The date the application was approved: January 14, 2009.

   FDA has verified the applicant's claim that NDA 22-256 was approved on January 14, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Anthony C. Tridico
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